DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

CDRH Medical Device Reporting
P.O. Box 3002
Rockville, MD 20847-3002

MEDICAL DEVICE REPORTING
SEMIANNUAL USER FACILITY REPORT

PART 1 - COVER SHEET

OMB: 0910-0059
Exp. Date: 02/28/99

If MDR reports were not submitted to either the FDA or a device manufacturer during this reporting period, DO NOT submit a semiannual report.

PART 1 INSTRUCTIONS

Complete one copy of the following information as a cover page for the semiannual report and return to the address listed above. This report should NOT include reports that are not required but have been submitted voluntarily.

1. REPORT PERIOD

☐ JAN - JUN __ __ __ __ (Y Y Y Y)

☐ JUL - DEC __ __ __ __ (Y Y Y Y)

2. USER FACILITY ID (HCFA OR FDA PROVIDED NUMBER)

3. USER FACILITY INFORMATION

a. Name

b. Street Address

c. City d. State e. ZIP Code

f. Country/Postal Code *(if not U.S.)*

4. USER FACILITY CONTACT INFORMATION

a. Name

b. Street Address

c. City d. State e. ZIP Code

f. Country/Postal Code *(if not U.S.)*

g. Telephone Number *(Include area code and extension)*

( )

5. TOTAL NUMBER OF REPORTS ATTACHED OR SUMMARIZED _____

a. Lowest Report Number _____ - _____ - _____
(HCFA or FDA Provided No.) *(Year)* *(Sequence No.)*

b. Highest Report Number _____ - _____ - _____
(HCFA or FDA Provided No.) *(Year)* *(Sequence No.)*

For each report in the range of report numbers listed above, attach a completed copy of Part 2 of this form, or a photocopy of the completed MedWatch FDA Form 3500A for the event that was sent to FDA and/or the manufacturer. In addition, attach a sheet listing report numbers in the above range that are not included in this report and explain why.

6. SIGNATURE OF CONTACT

7. DATE OF REPORT

__ __ / __ __ / __ __ __ __ (M M / D D / Y Y Y Y)

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

DHHS Reports Clearance Officer, Paperwork Reduction Project (0910-0059)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

(Please **DO NOT** RETURN this form to this address.)

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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PART 2 - SUMMARY OF EVENT

PART 2 INSTRUCTIONS

If photocopies of previously submitted FDA Form 3500A (MedWatch) are not provided for each MDR reportable event, complete one copy of the following for each MDR report submitted to FDA and/or the manufacturer during the six-month reporting period covered by this Semiannual Report.

1. USER FACILITY EVENT REPORT NUMBER

_____ - _____ - _____
(HCFA or FDA Provided No.) *(Year)* *(Sequence No.)*

2. WHERE WAS REPORT SUBMITTED? *(Check all that apply)*

☐ FDA ☐ Manufacturer ☐ Distributor ☐ Other _____

3. MANUFACTURER INFORMATION	4. DEVICE INFORMATION
a. Name	a. Brand Name
b. Street Address	b. Common Name
c. City d. State e. ZIP Code	c. Model Number
f. Country/Postal Code *(if not U.S.)*	d. Serial Number
	e. Lot Number
	f. Catalog Number

5. BRIEF DESCRIPTION OF EVENT